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PRATER, P

158

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05/25/89

- ☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.                 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/> _____  |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-15 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-15 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being clearly anticipated by Janoff et al.

Janoff et al discloses the method of providing local anesthesia topically by the use of lipid encapsulated anesthetics.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained for an invention which is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-15 are rejected under 35 U.S.C. 103 as being unpatentable over Janoff et al in view of Haynes.

Janoff et al. (col. 10, lines 50-65) indicates that any bioactive agent may be trapped in the liposomes of

his invention. These liposomes may then be used as local anesthetics (col. 10, line 61). Topical application is disclosed in col. 11, line 2. Janoff et al indicates that his vesicles may be unilamellar or multilamellar, as applicant discloses in claims 2, 6, 13-14. Janoff et al does not disclose the multivesicular vesicles of claim 15, however.

Phospholipids are disclosed in col. 4, lines 52-54 of Janoff et al. The applicant makes similar disclosures in claims 7-9.

Haynes discloses the non-topical delivery of local anesthetics encapsulated in microdroplets. The lipids used in these microdroplets (col. 6, lines 28-33) are similar to those of applicant's claims 7-9. Janoff et al does not name the bioactive agents which may be encapsulated in his invention specifically. Haynes specifically discloses benzocaine as a local anesthetic which may be incorporated into a liposome (col. 7, lines 60-63). The applicant makes similar disclosures in claims 3, 10 and 12.

The ranges and percentages disclosed in claims 4, 11 and 12 appear to be the result of routine experimentation by one of ordinary skill in the art of liposome encapsulation and should be supported by the submission of comparative data.

The motivation to combine Janoff et al and Haynes stems from the fact that both patents are

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concerned with the encapsulation of local anesthetics in liposomes or related vesicles. It would have been obvious to one of ordinary skill in the liposome encapsulation arts, that benzocaine or other local anesthetics such as those disclosed by applicant might be applied to the invention of Janoff et al.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kaswan and Carey et al are added as further examples of the use of liposomes to encapsulate anesthetics.

Any inquiry concerning this communication should be directed to Prater at telephone number 703-557-6525.



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